

## REMARKS

Claims 21-52 are now pending in the application. Claims 21-47 stand rejected. Claims 1-20 have been previously cancelled. Claims 21, 24, 28 and 37 have been amended herein. Claims 48-52 are new. Support for the amendments and new claims can be found throughout the application, drawings and claims as originally filed and, as such, no new matter has been presented. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments, remarks and new claims contained herein.

### REJECTION UNDER 35 U.S.C. § 102

Claims 21-25 and 28-34 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Harari et al. (U.S. Pat. No. 6,328,744; hereinafter "Harari"). This rejection is respectfully traversed.

Initially, Applicants note that Harari discloses a bone boring device that includes rigid needles for boring through the bone. Harari discloses that the needles are pushed into the bone. In

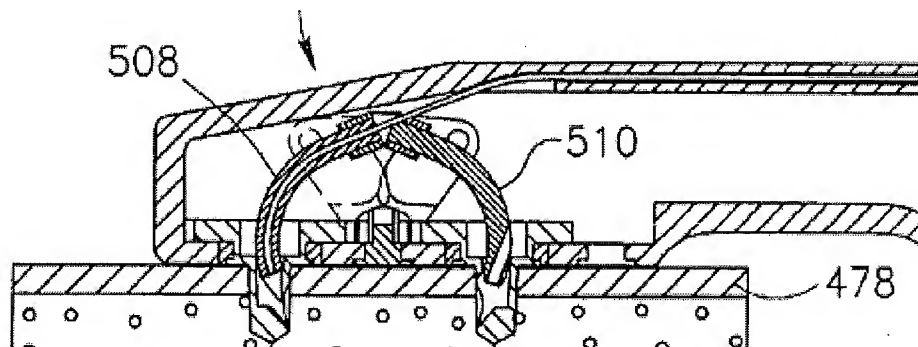
Figs. 17A-17D,

Harari discloses two

drill bits 504

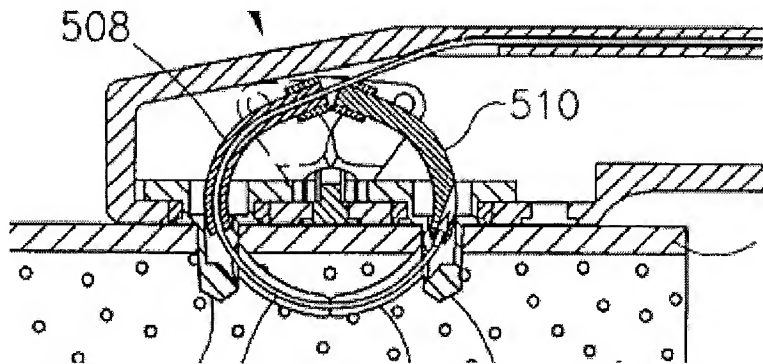
coupled adjacent to

needles 508,



510/520. The drill bits 504 are used to drill two linear apertures 540 in the bone, as illustrated above in the reproduction of Fig. 17B. Then, the needles 508, 510/520 are

pushed into the medulla to form a curved bore 542 in the anatomy. The needle 508 is a bored needle, which enables a thread 534 to pass therethrough. The thread 534 is coupled to a detachable tip 530. The needle 510/520 is a solid needle, with only an aperture 532 denned in its tip, which is sized to receive the tip 530 to draw the tip 530 out of the anatomy. Thus, Harari teaches the formation of a curved bore in a medulla with the use of two rigid arcuate needles, which are pushed into the anatomy until they meet at a midway point. At the midway point, since the detachable tip 530 extends beyond the end of the needle 508, the detachable tip 530 is forced into the denned aperture 532 of the needle 510/520. Then, the needles 508, 510/520 are removed from the anatomy, by being drawn backward out of the cut bore. As the detachable tip 530 is captured within the denned aperture 532, the backward movement of the needle 510/520 draws the detachable tip 532 and the thread 534 through the remainder of the curved bore. Thus, upon the removal of the solid needle 510/520 from the anatomy, the curved bore is threaded, as illustrated in the above reproduction of Fig. 17D. In contrast to Harari, independent Claim 21 has been amended to recite:



**...cutting a non-linear path with the flexible single shaft cutting tool through the bone structure from the first bone location to the second bone location so as to cause the flexible single shaft cutting tool to enter the bone structure at the first bone location and exit the bone structure at the second bone location (emphasis added).**

Independent Claim 28 has been amended to recite:

...drilling into the bone structure with the drill head **at an entering position;**

guiding the drill head with the flexible drill shaft with a guide mechanism along a **selected non-linear cutting path within the bone structure;** and

forming the selected non-linear cutting path with the drill head **between the entering position into the bone structure and an exiting position out of the bone structure** that is spaced a distance from the entering position in the bone structure (emphasis added).

In view of the above discussion, Applicants assert that Harari does not teach, suggest or disclose each and every element of independent Claims 21 and 28. With regard to Claim 21, Harari does not teach, suggest or disclose **cutting a non-linear path with the flexible single shaft cutting tool** through the bone structure from **the first bone location to the second bone location** so as to cause the flexible single shaft cutting tool to **enter** the bone structure **at the first bone location** and **exit** the bone structure **at the second bone location**, as claimed. Harari also does not teach, suggest or disclose drilling into the bone structure with the drill head at an entering position, guiding the drill head with the flexible drill shaft with a guide mechanism along a selected non-linear cutting path within the bone structure, or forming the selected non-linear cutting path with the drill head **between the entering position into the bone structure and an exiting position out of the bone structure** that is spaced a distance from the entering position in the bone structure, as claimed in Claim 28. Rather, Harari teaches the use of **two** rigid needles, which penetrate the bone structure at two distinct locations to form an arcuate path. Even if the rigid needles were considered to be **flexible** single shaft cutting tools, Harari teaches that these rigid needles then exit the

bone structure by being withdrawn through their respectively cut arcuate path. Neither of the rigid needles cut the bone from a first bone location to a second bone location in which the rigid needles exit the bone at the second bone location or exit an exiting position, which is spaced apart from an entering position, as claimed. In addition, Applicants note that to modify Harari to include a flexible single shaft cutting tool or drill head that can cut a non-linear cutting path from an entering position to an exiting position, as it would improperly modify the principle of operation of Harari, specifically the operation of the device 500. MPEP 2143.01.

Accordingly, in view of at least the above discussion, Applicants respectfully submit that Harari does not teach, suggest or disclose each and every element of Claims 21 and 28, and thus, Applicants respectfully request the Office to reconsider and withdraw the rejection of Claims 21 and 28 under 35 U.S.C. § 102(b).

In addition, since Claims 22-24 and 29-34 depend directly or indirectly from either independent Claim 21 or 28, Claims 22-24 and 29-34 should be in condition for allowance for at least the reasons set forth for Claims 21 and 28 above. Additionally, Claim 24 is believed to have independently allowable subject matter as Harari does not teach, suggest or disclose pulling a suture through the non-linear path to secure a suture to a selected tissue near to the first and second bone location after the non-linear path has been formed. Claim 30 is believed to have independently allowable subject matter as Harari does not teach, suggest or disclose a guide mechanism that includes a flexible rod at least partially enclosing at least a portion of the flexible drill shaft that is coupled to the flexible drill shaft at a proximal end. Claim 31 is also believed to have independently allowable subject matter as Harari does not teach, suggest or disclose

positioning at least a portion of the flexible drill shaft through a flexible rod, connecting a flexible member to a portion of the flexible drill shaft and sliding a handle to tension the flexible member to assist in directing the flexible drill shaft along the selected non-linear path.

With regard to Claim 32, Applicants also note that Claim 32 is believed to have independently allowable subject matter as Harari does not teach, suggest or disclose that sliding the handle to tension the flexible member moves the flexible member to engage the drill head or the flexible drill shaft to move the drill head from the selected first path to the selected second path during forming the selected non-linear cutting path. Claim 33 is also believed to have independently allowable subject matter as Harari does not teach, suggest or disclose directing at least one of the flexible drill shaft, the drill head or combinations along a first path and directing at least one of the flexible drill shaft, the drill head or combinations along a second path.

Accordingly, Applicants respectfully request the Office reconsider and withdraw the rejections of Claims 22-24 and 29-34 under 35 U.S.C. § 102(b).

#### **REJECTION UNDER 35 U.S.C. § 103**

Claims 26 and 35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Harari. This rejection is respectfully traversed.

Applicants note that Claims 26 and 35 depend directly or indirectly from independent Claims 21 or 28, and thus, Claims 26 and 35 should be in condition for allowance for at least the reasons set forth for Claims 21 and 28 above. In this regard, Applicants note that Moore does not provide any further teachings that overcome the

shortcomings of Harari, which were identified in the remarks regarding Claim 21, above. Accordingly, Applicants respectfully request the Office reconsider and withdraw the rejection of Claims 26 and 35 under 35 U.S.C. § 103(a).

Claims 36-41 and 43-47 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Harari further in view of Hyde (U.S. Pat. No. 6,589,281; hereinafter "Hyde"). This rejection is respectfully traversed.

Applicants respectfully refer the Office to the remarks regarding Claims 21-25 and 28-34 for a discussion of the Harari reference. With regard to Hyde, Applicants note that Hyde discloses a transosseous core approach to access an articulating surface. Hyde teaches drilling a core through a first bone A with a non-articular surface 8A such that the core or bone hole CH1 is adjacent to an articular surface 1A of a second bone B. The drilling of the bone hole CH1 enables the treatment of the articular surface 1A as tools can pass through the bone hole CH1. Hyde does not teach, suggest or disclose the use of any type of guide mechanism to form the bone hole CH1, let alone the use of a flexible guide mechanism. In contrast to Harari and Hyde, independent Claim 39 recites:

...guiding the drill head with a flexible guide mechanism though an entry position and through the identified bone structure **in a first direction**;  
forming a tunnel with the drill head along a first path and a second path;  
exiting the identified bone structure at an exit position with the drill head;  
moving a suture engaging member near the drill head though the formed tunnel;  
pulling a suture through the formed tunnel **in a second direction** to pull the suture **from the exit position to the entry position**...(emphasis added).

In view of the above discussion, Applicants assert that none of the cited references, singly or in combination, teach, suggest or disclose each and every element of Claim 39. In this regard, as discussed, Harari does not teach, suggest or disclose **guiding** a drill head (associated with the flexible drill shaft) with a **flexible guide mechanism** through an entry position and through the identified bone structure in a first direction, and pulling a suture through the formed tunnel **in a second direction** to pull the suture **from the exit position to the entry position**. Rather, Harari teaches pushing a first rigid arcuate needle 508 that includes a detachable tip 530 and thread 534 into an anatomy. A second rigid arcuate 510/520 needle is also pushed into the anatomy to receive the detachable tip 530 and thread 534 from the first arcuate needle 508 so that when the needles 508, 510/520 are removed from the anatomy, the curved bore formed in the anatomy is threaded (Fig. 17D). Thus, Harari teaches passing a rigid arcuate needle into a bone structure in a first direction, and then passing a suture along a first direction, from an entry position to an exit position, and not pulling a suture through a formed tunnel in a second direction to pull the suture from the exit position to the entry position, as claimed.

Hyde does not remedy this shortcoming of Harari. Hyde merely discloses the formation of one or more bone holes in an anatomy to reach an articular surface. Hyde does not teach, suggest or disclose pulling a suture through a formed tunnel in a second direction to pull the suture from the exit position to the entry position, as claimed.

Accordingly, in view of at least the above discussion, Applicants respectfully submit that Harari and Hyde, singly or in combination, do not teach, suggest or disclose each and every element of Claim 39, and thus, Applicants respectfully request the Office to reconsider and withdraw the rejection of Claim 39 under 35 U.S.C. § 103(a). In addition, since Claims 36-38, 40, 41 and 43-47 depend directly or indirectly from either independent Claim 28 or 39, Claims 36-38, 40, 41 and 43-47 should be in condition for allowance for at least the reasons set forth for Claims 28 and 39 above. Further, Claim 37 is believed to have independently allowable subject matter as the cited art does not teach, suggest or disclose moving a suture through the tunnel formed in the humerus after the tunnel is formed. In addition, Applicants note that Claim 38 includes independently allowable subject matter as the cited art does not teach, suggest or disclose associating a suture engaging hook with the drill head. Additionally, Claim 43 is believed to have independently allowable subject matter as the cited art does not teach, suggest or disclose a flexible guide mechanism that includes a flexible rod that is coupled to the flexible drill shaft at a proximal end. Claim 44 is also believed to have independently allowable subject matter as the cited art does not teach, suggest or disclose connecting a flexible member to a portion of the flexible drill shaft and sliding a handle to tension the flexible member to direct the flexible drill shaft along the selected curved path while forming the tunnel.

Accordingly, Applicants respectfully request the Office reconsider and withdraw the rejections of Claims 36-38, 40, 41 and 43-47 under 35 U.S.C. § 103(a).



Claim 42 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Harari in view of Hyde and further in view of Moore et al. (U.S. Pat. No. 4,872,451; hereinafter "Moore"). This rejection is respectfully traversed.

Applicants note that Claim 42 depends directly from independent Claim 39, and thus, Claim 42 should be in condition for allowance for at least the reasons set forth for Claim 39 above. In this regard, Applicants note that Moore does not provide any further teachings that overcome the shortcomings of Harari and Hyde, which were identified in the remarks regarding Claim 39, above. Accordingly, Applicants respectfully request the Office reconsider and withdraw the rejection of Claim 42 under 35 U.S.C. § 103(a).

#### **NEW CLAIMS**

Claims 48-52 are new. Support for this claim can be found through the specification, drawings and claims as originally filed, and in at least paragraph [0023] and Figs. 1-5, and thus, Applicants respectfully submit that no new matter has been added. In addition, Applicants respectfully assert that Claim 48 is patentable and in condition for allowance as the cited art does not teach, suggest or disclose extending a flexible single shaft cutting tool having a continuous drill shaft through the bone structure from the first bone location to the second bone location, as claimed. Claim 49 is also believed to be patentable and in condition for allowance as the cited art does not teach, suggest or disclose flexing the single shaft cutting tool from a first configuration to a second configuration. Claim 50 is believed to be patentable and in condition for allowance as the cited art does not teach, suggest or disclose flexing the flexible member from a first configuration to a second configuration with the handle. Further, Claim 51 is believed to

be patentable and in condition for allowance as the cited art does not teach, suggest or disclose pulling the suture through the formed tunnel in the second direction after the tunnel is formed. Claim 52 is also believed to be patentable and in condition for allowance as the cited art does not teach, suggest or disclose that the second direction is opposite the first direction, as claimed. Prompt and favorable consideration of new Claims 48-52 is hereby respectfully requested.

### CONCLUSION

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

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